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Message: 2 page - Statement of Substance
of InterviewS/N: 09/040,518Filed: March 17, 1998

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Roger C. Rich
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of:	Karatzas <i>et al.</i>	Confirmation No.:	1912
Serial No.:	09/040,518	Art Unit:	1632
Filed:	March 17, 1998	Examiner:	Falk, Anne Marie
For:	PRODUCTION OF BIOFILAMENTS IN TRANSGENIC ANIMALS	Attorney Docket No:	9529-009-999 (06632/011001)

STATEMENT OF SUBSTANCE OF INTERVIEW

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Applicants thank Examiner Anne Marie Falk for the interview on October 4, 2004, and hereby submit a recordation of the substance of the interview within one month of the date of mailing of the Interview Summary Form.

The written description rejection as it applies to Claim 39 was discussed. Applicants ascertained that the Examiner understood the term "*in vivo* somatic cell gene transfer" to refer only to gene transfer to *somatic* cells of an animal. As discussed below, Claim 39 does not encompass animals into which a transgene has been transferred only to somatic cells but not to germ cells of the animal.

With regard to the discussion on mosaic animals versus chimeric animals, it was noted that the specification states: "The microinjected zygotes are transferred to an appropriate female resulting in the birth of a transgenic or chimeric animal, depending upon the stage of development when the transgene is integrated. Chimeric animals can be bred to form true germline transgenic animals." Specification, Example 8, page 26, lines 17-20. As summarized in the Interview Summary mailed October 8, 2004, the Examiner contended that the reference to chimeric animals appears to be wrong or confused, and further alleged that "it is not apparent that Applicants intended to refer to mosaic animals instead." Applicants

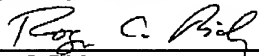
disagreed with the Examiner and asserted that one of skill in the art would readily appreciate that the term "chimeric" when read in the context of the specification was intended to take the ordinary, accepted meaning of the term "mosaic." Applicants respectfully submit that this point is moot because Claim 39 recites a "*transgenic female ruminant...*" In particular, in context of the specification, the term "transgenic" refers to an animal with a transgene in its genome in both somatic and germ cells. See Specification, page 7, lines 17-25, and page 26, lines 16-20. However, to be clear, Claim 39 has been amended to explicitly recite that which has always been intended as part of the claim, *i.e.*, that the transgenic female ruminant comprises "*germline and somatic cells that comprise the nucleic acid molecule*"

No discussion regarding the written description rejection on the nucleic acids took place, other than the fact that Applicants' Attorney stated that an appropriate response was to be formulated.

With regard to the enablement issues, the Attorney stated that he intended to submit a Declaration to address the Examiner's outstanding questions regarding the transgenic animals, and asked if the Examiner would consider such a declaration. The Examiner indicated that she would. Applicants' Attorney mentioned that it should not be difficult to produce a declaration since, to his knowledge, at least 100 transgenic animals have been generated, using more than one regulatory sequence, and that many of the females generated of which have produced multi-gram quantities of biofilament protein. Applicants will shortly submit a declaration.

Respectfully submitted,

Date: November 8, 2004


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